

U.S. Department of Justice

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For Immediate Release:

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July 10, 2006

EVENT: Guilty Plea

Defendant: Dr. Eric Seiger, The Skin and Vein Center

SKIN AND VEIN CENTER PLEADS GUILTY TO IMPORTATION OF NON-FDA APPROVED MEDICAL DEVICES

The Skin and Vein Center (a/k/a "Dermatology Pathology, P.C.") with offices located in Troy, Westland, Southfield, and Fenton, Michigan, pleaded guilty to unlawful importation of goods into the United States, announced United States Attorney Stephen J. Murphy. The plea was entered on behalf of the company by Dr. Eric Seiger, a 50% shareholder in the Skin and Vein Center (SVC), today before the Hon. Denise Page Hood.

U.S. Attorney Murphy was joined in the announcement by Michael E. Cleary, Special Agent in Charge Food and Drug Administration, Office of Criminal Investigations (FDA) and Brian M. Moskowitz, Special Agent in Charge, U.S. Customs and Border Protection (ICE).

Dr. Eric Seiger, previously entered a guilty plea on July 5, 2006, in United States District Court before Judge Denise Page Hood. Seiger pleaded guilty to the misdemeanor offense of introducing a misbranded medical device into commerce.

"Members of the public must be able to trust that their doctor will not be administering drugs or treatments that are not approved by the FDA. Medical professionals, above all, will be held accountable if they intentionally misuse or administer unapproved drugs. I commend the FDA's Office of Criminal Investigations, and ICE for their excellent investigation that led to this prosecution," said United States Attorney Murphy.

The FDA Office of Criminal Investigations, under the direction of Special Agent in Charge Michael E. Cleary, Chicago Field office remains committed to working with their partners in law enforcement to protect the public's health and safety.

According to Brian M. Moskowitz, Special Agent in Charge of the Immigration and Customs Enforcement, Office of Investigations in Detroit, "these guilty pleas are the result of an aggressive investigative partnership between the FDA and ICE. There is an obvious safety concern regarding the illegal importation and subsequent utilization of unlicensed medications and /or medical devices. ICE will continue to aggressively pursue individuals and organizations involved with the illegal importation of goods that may jeopardize the safety of our communities."

Skin and Vein Center ("SVC") is engaged in the business of providing office-based dermatological surgery and care, hair transplantation and varicose vein treatment. SVC is owned and managed by Dr. Sandy Goldman and Dr. Eric Seiger.

On September 2, 2004, federal agents executed search warrants at SVC's four business locations. At the time of the execution of the warrant at the Fenton location, the office manager, knowing that the agents were searching for Perlane, attempted to hide quantities of Perlane in a locked shredder box in order to prevent the agents from discovering and seizing the Perlane. Perlane is a substance that was not then approved by the FDA, and was being used a dermatological filler to enlarge lips or reduce wrinkles.

Beginning in 2003, SVC unlawfully imported the medical devices Restylane and Perlane to the United States and administered them to its patients. Both Restylane and Perlane are temporary dermatological fillers administered via injection to enhance the recipient's appearance by, for example, enlarging the lips or minimizing facial lines and wrinkles.

Restylane and Perlane are classified under federal law as a Class III medical devices.

Restylane was first approved by the United States Food and Drug Administration ("FDA") on December 12, 2003. Perlane was not approved by the FDA for any purpose prior to September 4, 2004. Prior to those respective times, as unapproved Class III medical devices, it was illegal to import or introduce Restylane or Perlane into commerce.

Knowing that Perlane and Restylane were not approved by the FDA, and knowing that their distributor would not ship either device to the United States, Seiger initiated a scheme to obtain Perlane via Canada.

Initially, Seiger made arrangements for shipments of Restylane and Perlane to be delivered to a location in Windsor, Canada. On two occasions, Seiger sent a SVC employee to Windsor to pick up the packages of Restylane and Perlane and bring the packages back to SVC's Troy location. On each occasion, Seiger paid the employee \$100 in cash from his personal funds. Seiger gave the employee explicit instructions to deny knowledge of the contents of the packages in the event the employee was questioned by U.S. Customs officials.

Seiger made arrangements for Restylane and Perlane to be shipped directly to SVC via a dentist's office in Pickering, Ontario. Whenever SVC needed more Restylane and Perlane, Seiger contacted the distributor directly and, while claiming to be a representative of the dentist's office, ordered more Restylane and Perlane on the dentist's account. After the Restylane and Perlane arrived at the dentist's office, an employee of the dentist would ship the Restylane and Perlane to SVC's Troy location. On some such occasions, the employee mislabeled the packages as containing dental bleach.

The count to which SVC pleaded guilty carries a maximum sentence of a \$500,000 fine. The count to which Seiger pleaded guilty carries a maximum sentence of 1 year imprisonment and/or a \$100,000 fine.

As part of the agreements reached with the government, SVC has agreed to forfeit \$412,048.61 to the United States Government.

The sentencing for Seiger and SVC is scheduled for November 9, 2006.

Mr. Murphy commends the excellent work of the FDA/OCI and Immigration and Customs Enforcement agents in this investigation. The case was prosecuted by Assistant United States Attorney Sarah Resnick Cohen.